

REMARKS

Claims 1-25 are pending in this application. Claims 5, 12-17, and 22-25 are withdrawn from consideration. Claims 1-4, 6-11, and 18-21 have been examined and stand rejected. Claim 1 has been amended and new Claims 26-37 have been added. No new matter has been introduced. Reconsideration and allowance of Claims 1-4, 6-11, and 18-37 is respectfully requested.

The Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1-4, 6-11, and 18-21 under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, the term "new" in the preamble of Claim 1, from which Claims 2-4, 6-11, and 18-21 depend, is unclear. Applicant has amended the preamble of Claim 1 delete the term "new." Withdrawal of this ground of rejection is respectfully requested.

The Rejection of Claims Under 35 U.S.C. § 102(e)(2)

The Examiner has rejected Claims 1-4, 6-11, and 18-21 under 35 U.S.C. § 102(e)(2) as being anticipated by U.S. Patent No. 6,368,794 (Daniel et al.). According to the Examiner, Daniel describes monitoring altered gene expression, the detection of gene expression using nucleic acid microarray hybridization, the preparation of multiple profiles of different cell parameters, and monitoring analyte treatment efficacy. Applicant respectfully disagrees.

Daniel et al. neither discloses nor suggests applicant's claimed invention for the following reasons. Claim 1, from which Claims 2-4, 6-11, and 18-21 depend, and new Claims 26 and 32, from which Claims 27-31 and 33-37, respectively, depend, are directed to methods for discovering compounds with expression profile-altering activity. The method of Claim 1 comprises four steps:

- (a) determining a first expression profile of a set of representative molecules in a first biological sample;

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(b) determining a second expression profile of the set of molecules in a second biological sample, wherein the second biological sample differs from the first biological sample by a known parameter;

(c) determining a third expression profile of the set of molecules in the second biological sample after treatment of the second biological sample with at least one analyte of previously uncharacterized specific pharmacological activity; and

(d) comparing the third expression profile with the first and second expression profiles to identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is the second expression profile

The method of new Claim 26 comprises three steps:

(a) determining a first expression profile of a set of representative molecules in a biological sample after treatment of the biological sample with a known drug;

(b) determining a second expression profile of the set of molecules in a biological sample after treatment of the biological sample with at least one analyte of previously uncharacterized specific pharmacological activity; and

(c) comparing the first expression profile with the second expression profiles to identify one or more analytes that induces an expression profile that is similar to the first expression profile.

The method of new Claim 32 comprises four steps:

(a) determining a first expression profile of a set of representative molecules in a first biological sample;

(b) determining a second expression profile of the set of molecules in a second biological sample, wherein the second biological sample differs from the first biological sample by a drug treatment;

(c) determining a third expression profile of the set of molecules in a third biological sample after treatment of the third biological sample with at least one analyte of previously uncharacterized specific pharmacological activity; and

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(d) comparing the third expression profile with the first and second expression profiles to identify one or more analytes that induces a third expression profile that is more similar to the first expression profile than is the second expression profile.

Support for the method of new Claims 26-37 can be found throughout the specification, for example, at page 1, line 21 to page 2, line 6, page 3, lines 28-30; page 5, lines 23-25; page 8, line 23 to page 9, line 8; page 12, lines 11-12; page 12, line 29 to page 13, line 4; and page 15, lines 1-8.

Daniel et al. neither discloses nor suggests determining an expression profile in a biological sample after treating the biological sample with at least one analyte of previously uncharacterized specific pharmacological activity, as recited in step (c) of Claim 1 or step (b) of Claim 26. Moreover, Daniel et al. does not disclose or suggest comparing this expression profile with other expression profiles in order to identify analytes that induce an expression profile that is more similar to a specific expression profile, as recited in step (d) of Claim 1 or step (c) of Claim 26.

As pointed out by the Examiner, Daniel et al. state that microarrays can be used in "diagnosing, prognosing, or monitoring the treatment of a disease" (column 2, lines 43-45). However, applicant's inventive methods are not directed to monitoring or evaluating the course of existing disease treatments. Rather, applicant's invention is directed to the discovery of compounds with expression profile-altering activity. For these reasons, Daniel et al. does not disclose or in any way suggest the invention of Claims 1-4, 6-11, and 18-31. Because the cited reference fails to exactly describe the claimed invention, the reference is not anticipatory. Withdrawal of the rejection is respectfully requested.

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CONCLUSION

In view of the foregoing amendments and remarks, Claims 1-4, 6-11, and 18-37 are believed to be in condition for allowance. If any issues remain that can be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicant's attorney at 206.695.1783.

Respectfully submitted,

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